

REMARKS

Claims 17, 20, 21, and 40 presently appear in this case. No claims have been allowed. The official action of November 14, 2006, has now been carefully studied.

Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to an RNA molecule that targets mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO:10. The targeting preferably prevents processing, splicing, transport or translation of the mRNA or results in mRNA degradation. The RNA may be an antisense RNA or a ribozyme.

The examiner has commented on the effective filing date for the various claims. Applicant chooses not to respond to these comments of the examiner in view of the fact that no intervening reference has been cited. If and when the effective filing date of the claims becomes critical, then applicant reserves the right to explain why the claims are entitled to an earlier filing date.

The examiner states that the effective filing date of instant claims 17, 20, 21 and 40-43 is considered to be the filing date of the amendment filed on September 8, 2006. Applicant invites the examiner to cite authority from the MPEP or elsewhere, which states that the effective filing date of an amendment can be other than the effective filing date of

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the application in which it was filed. Applicant is aware of no procedure in which the filing of a new oath or declaration can change the filing date of an application without the filing of a CIP. It is noted that MPEP 2143.03 states that all limitations of the claims must be considered and given weight including limitations which the examiner does not consider to be supported in the specification as originally filed.

The examiner has objected to the oath or declaration because the amendment filed on March 17, 2004, allegedly introduced claims with no support under 35 U.S.C. 112, and the amendment was not filed on the filing date of the instant application. This requirement is respectfully traversed.

Even assuming the examiner is correct that the claims contain new matter, this cannot be resolved merely by filing a new declaration. In any event, the alleged new matter has now been removed from the claims, thus obviating this requirement.

The examiner has objected to abstract because it has more than 150 words. Correction has been required.

By the present amendment, a new abstract has been added, which is more closely directed to the invention as now claimed and that has fewer than 150 words. Accordingly, this objection has now been obviated.

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The examiner states that the status of the priority applications on page 1 needs updating.

Paragraph [0001] of the specification has now been amended to comply with the examiner's requirement.

Claims 42 and 43 have been objected to because the examiner considers the phrase "an RNA molecule in accordance with claim" as an improper phrase for a dependent claim. The examiner states that replacing the term "an" on line 1 with the term -- the -- would be corrective.

Claims 42 and 43 have now been deleted, thus obviating this objection. However, the examiner is incorrect that claims 42 and 43 were informal. 35 U.S.C. 112 states that a claim may be written in independent or, if the nature of the case admits, in dependent form. A dependent claim is merely a shorthand way of writing an independent claim with all of the subject matter of the independent claim incorporated therein by reference. If an independent claim can begin "An RNA", then a dependent claim can as well, as each dependent claim is an independent claim written in shorthand form. Furthermore, the examiner's attention is invited to the examples of acceptable claim language set forth in MPEP 608.01(n). Each of these acceptable dependent claims begins with "A gadget."

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The examiner states that if claim 20 is allowed it will have to be renumbered. Respectfully, this is the responsibility of an examiner when preparing a case for allowance. Applicants are not involved in this task.

Claims 17, 20, 21 and 40-43 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner states that this is a new matter rejection. The examiner states that the specification does not disclose SEQ ID NO:10 or an RNA molecule that targets and is at least 95% homologous to mRNA consisting of RNA encoding a polypeptide having the amino acid sequence of SEQ ID NO:10. The examiner states that paragraph [0056] of the specification does not disclose an RNA molecule that targets and is at least 95% homologous to mRNA consisting of RNA encoding a polypeptide having the amino acid sequence of SEQ ID NO:10. The examiner says the same thing about paragraph [0058] of the specification.

In order to obviate this rejection, claims 17 and 40 have now been amended to delete reference to "at least 95% homology," and claims 41, 42 and 43 have been deleted because they would be duplicative of the claim 40, as amended. Accordingly, reconsideration and withdrawal of this rejection are respectfully urged.

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Claims 17, 20, 21 and 40-43 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner states that claims 17 and 21 are readable on a genus of RNA molecule that targets and is at least 95% homologous to mRNA consisting of RNA encoding a polypeptide having the amino acid sequence of SEQ ID NO:10, wherein the targeting results in mRNA degradation. The examiner states that the genus of RNA molecules is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made. The examiner states that claims 20 and 40-43 are readable on a genus that includes analogs having at least a 95% homology, wherein the genus is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made.

The examiner states that the term "mRNA" in the instant claims indicates that the term reads on pre-mRNA with introns or processed mRNA without introns. The examiner states that the skilled artisan would not be able to determine, without further experimentation, if a sequence having the required structure had a function that was considered essential for the claimed genus of RNA molecules. The examiner states that the mere teaching in the

specification of antisense is not sufficient to support the presently claimed invention directed to a genus of RNA molecules with the desired biological activity. The examiner states that applicant is attempting to preempt the future before it has arrived. The examiner states, without explaining, that the claims embrace cDNA and genomic DNA. This rejection is respectfully traversed.

The claims have now been amended to delete reference to analogs having at least 95% homology. Accordingly, the claims are now directed to antisense RNA molecules that are entirely homologous to the target mRNA, or the complement of at least seven nucleotides of target mRNA encoding a specific polypeptide. The present invention provides no new inventions with respect to antisense. The present invention is directed to the discovery of the novel polypeptide whose production it is desired to inhibit. Antisense technology is well developed and the present specification contains more than a mere mention that the invention includes antisense. Paragraphs [0058] and [0059], especially paragraph [0059], go into great detail about how one selects appropriate antisense molecules. Furthermore, many literature references are cited to show the state of the art of antisense production. With all of this disclosure, one of ordinary skill in the art would be able to practice the present invention without undue experimentation.

Applicant is not "attempting to preempt the future before it arrives." The mRNA sequence is provided in the present specification at SEQ ID NO:2. This is the mRNA that encodes the polypeptide of SEQ ID NO:10. The claims require the antisense RNA be homologous to or a complement of at least seven nucleotides of this nucleotide sequence. There is substantial direction given in the present specification as to how to determine whether any such sequence will be operable or not. Certainly, if SEQ ID NOS:2 and 10 were known to the prior art, the examiner would not hesitate in making a rejection of antisense claims, stating that it would be obvious to make antisense, given the known mRNA sequence and polypeptide sequences. Thus, the time to get a patent on antisense sequences is when the novel polypeptide and mRNA are disclosed, not at some future date when all such antisense claims would be considered obvious.

The present specification recognizes that some complementary sequences will not result in mRNA degradation or in prevention of processing, splicing, transport or translation. However, the present specification teaches how to determine which ones will work. This is well within the skill of one of ordinary skill in the art and therefore the present inventors were indeed in possession of such operable antisense molecules and should be able to claim them.

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Reconsideration and withdrawal of this rejection is
respectfully urged.

It is noted that all of the remaining previous
rejections have been withdrawn.

It is submitted that all of the claims now present
in the case clearly define over the references of record and
fully comply with 35 U.S.C. 112. Reconsideration and
allowance are therefore earnestly solicited.

Respectfully submitted,

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